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Pelvic floor symptoms in women receiving peritoneal dialysis

Submission date
27/05/2025

Recruitment status
Recruiting

Registration date
05/06/2025

Overall study status
Ongoing

Last Edited
05/06/2025

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Peritoneal dialysis is normally carried out at home. This gives the person some flexibility over work, study, and other activities. Because peritoneal dialysis involves the dwelling and exchange of dialysis fluid within the abdomen, the increased pressure may lead to problems in the pelvic floor muscles, such as pelvic floor prolapse. Such problems may be more common in women who have given birth, are or have been overweight.
The pelvic floor is made up of muscles that form a sling from the front to the back to the back of the pelvis. They provide support to the organs within the pelvis and play a role in controlling your bladder, bowel and sexual functions. Pelvic floor prolapse refers to a bulging of bowel, bladder or womb into or outside of the vagina. There have been a few reports of this problem in women who receive peritoneal dialysis. However, we do not know how common it is or how it affects daily living.
The aim of this pilot study is to test questionnaires in women receiving peritoneal dialysis, which ask about pelvic floor symptoms. The information we receive will help us with the design of a larger study.

Who can participate?
Women aged between 18 and 90 years who are receiving peritoneal dialysis

What does the study involve?
The study involves completing questionnaires that ask about the presence of pelvic floor symptoms and how they affect daily life. These will be completed at the start of the study and after 6 months.

What are the possible benefits and risks of participating?
While we do not expect that there will be direct health benefits, symptoms or other health issues may be identified from completing the questionnaires. The doctor will be informed so that treatment or referral for help can be arranged.
The risk is that the study questionnaires may touch on sensitive topics. Psychological support will be provided where there is distress as a result of participating in the study.

Where is the study run from?
University Hospitals of Leicester NHS Trust (UK)

When is the study starting and how long is it expected to run for?
April 2025 to September 2026

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Osasuyi Iyasere, osasuyi.iyasere@nhs.net

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
352200

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
EDGE ID - 176516

Study information

Scientific Title

Exploring pelvic floor symptoms in women receiving peritoneal dialysis – a pilot observational study

Acronym
EXPLORE PD

Study objectives
It is feasible to evaluate pelvic floor dysfunction in women receiving peritoneal dialysis (PD)

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/04/2025, Health and Social Care Research Ethics Committee A (HSC REC A) (Business Services Organisation Unit 4, Lissue Industrial Estate West Rathdown Walk Moira Road Lisburn BT28 2RF, Lisburn, BT28 2RF, United Kingdom; +44 (0)28 95 361404; RECA@hscni.net), ref: 25/NI/0046

Study design
Pilot single-centre prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Pelvic floor symptoms in women on peritoneal dialysis

Interventions
Pelvic floor questionnaires that examine the burden and impact of pelvic floor symptoms will be administered to eligible at baseline and after 6 months. Demographic and clinical data will also be captured during the study period.

Intervention Type
Other

Primary outcome measure

1. Study recruitment rate measured as a percentage at baseline
2. Study dropout rate measured as a percentage over 6 months follow-up
3. Questionnaire completion rates measured as pa ercentage at baseline and 6 months

Secondary outcome measures
1. Pelvic floor symptoms measured using the Pelvic Floor Distress Inventory (PDFI-20) at baseline and 6 months
2. Impact of pelvic floor symptoms on wellbeing measured using the Pelvic Floor Impact Questionnaire (PFIQ-7) scores at baseline and 6 months

Overall study start date
07/04/2025

Completion date
30/09/2026

Eligibility

Key inclusion criteria
1. Aged between 18 and 90 years
2. Receiving peritoneal dialysis
3. Female
4. Able to provide informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
90 Years

Sex
Female

Target number of participants
35

Key exclusion criteria
1. Unable to provide informed consent
2. Any other significant disease or disorder which, in the opinion of the patient’s own clinician, may put the participants at risk because of participation in the study. For example, a severe mental health disorder or recent bereavement

Date of first enrolment

15/05/2025

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust

Sponsor details
Research and Innovation
Leicester General Hospital
Gwendolen Road
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+44 (0)1162588239
UHLSponsor@uhl-tr.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.uhl-tr.nhs.uk/

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Osasuyi Iyasere (osasuyi.iyasere@nhs.net)

IPD sharing plan summary
Available on request